

### UNITED STATES PATENT AND TRADEMARK OFFICE

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES BOX INTERFERENCE, WASHINGTON, D.C. 20231

> Filed by: Fred E. McKelvey Telephone: (571) 272-9797 Facsimile: (571) 273-0042

MAILED

OCT - 7 2005

PAT. & T.M. OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES Applicants: Aronhime et al. Application No.: 09/997,126

Filed: 11/29/01

For: Novel crystal forms of

atorvastatin hemi-calcium and processes for their preparation as well as novel processes for preparing other forms

The above-identified application or patent has been forwarded to the Board of Patent Appeals and Interferences because it is adjudged to interfere with another application or patent. An interference has been declared. The interference is designated as No. 105,384.

Notice is hereby given the parties of the requirement of the law for filing in the Patent and Trademark Office a copy of any agreement "in connection with or in contemplation of the termination of the interference." 35 U.S.C. § 135(c).

Fred E. McKelvey
Senior Administrative Patent Judge

### INTERFERENCE DIGEST

Interference No. 105,384	Paper No.
Name: Judith Aronhime et al.	
Serial No.: 09/997,126	Patent No.
Title: Novel crystal forms of atorvastatin hemi-calcium and processes for their preparation as well as novel processes for preparing other forms	
Filed: 11/29/01	
Interference with Byrn et al.	
DECISION ON MOTIONS	
Administrative Patent Judge,	Dated,
EVALA DEGRACA	
FINAL DECISION	
Board of Patent Appeals and Interferences,	Dated,
Count	
Court,	Dated,
REMARKS	

Mail Stop Interference

P.O. Box 1450

Alexandria Va 22313-1450

Tel: 571-272-9797 Fax: 571-273-0042 Filed 7 October 2005

#### UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

STEPHEN ROBERT BYRN, DAVID ANDREW COATES, KAREN SUE GUSHURST, JOSEPH FRANCIS KRZYZANIAK, ZHENG JANE LI, HENRY GRANT MORRISON II, AERI PARK and PETINKA IVANOVA VLAHOVA,

Junior Party (Patent 6,605,729 B1),

ν.

MAILED

OCT - 7 2005

PAT. & T.M. OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

JUDITH ARONHIME, RAMY LIDOR-HADAS, VALERIE NIDDAM, REVITAL LIFSHITZ and GUY SAMBURSKY,

Senior Party (Application 09/997,126).

Patent Interference No. 105,384-McK Technology Center 1600

### DECLARATION - Bd.R. 203(d)

### Part A. Declaration of interference

An interference is declared (35 U.S.C. § 135(a)) between the above-identified parties. Details of the application, patent, count and claims designated as corresponding or as not corresponding to the count appear in Parts E and F of this DECLARATION.

### Part B. Judge managing the interference

Administrative Patent Judge McKelvey has been designated to manage the interference. 37 CFR § 41.104(a) [Bd. R. 104(a)].

### Part C. Standing order

A Trial Section STANDING ORDER (Paper 2) accompanies this DECLARATION. The STANDING ORDER applies to this interference.

#### Part D. Initial conference call

A telephone conference call to discuss the interference is set for 1:30 p.m. (1330 hours Eastern Time) on Monday, 21 November 2005 (the Board will initiate the call).

No later than **two business days (i.e., Thursday, 17 November 2005)** prior to the conference call, each party shall file and serve by facsimile (STANDING ORDER ¶ 4.5) a list of the motions (Bd. R. 120; Bd. R. 204; STANDING ORDER ¶ 26) the party intends to file.

A sample schedule for taking action during the motion phase appears as Form 2 in the STANDING ORDER. Counsel are encouraged to discuss the schedule prior to the conference call and to agree on dates for taking action. A typical motion period lasts approximately eight (8) months. Counsel should be prepared to justify any request for a shorter or longer period.

### Part E. Identification and order of the parties

#### Junior Party

Named inventors:

Stephen Robert Byrn West Lafayette, IN

David Andrew Coates West Lafayette, IN

Karen Sue Gushurst Lafayette, IN

Joseph Francis Krzyzaniak,

Pawcatuck, CT

Zheng Jane Li Quaker Hill, CT

Henry Grant Morrison II

Lafayette, IN

Aeri Park

West Lafayette, IN

Petinka Ivanova Vlahova

Lafayette, IN

Patent:

U.S. Patent 6,605,729 B1 issued 12 August 2003

based on application 10/184,669

filed 28 June 2002

Title:

Crystalline forms of  $[R, -(R^*, R^*)]$  - 2-(4-fluorophenyl)- $\beta$ ,  $\delta$ -dihydroxy-5-

(1-methylethyl) -3-phenyl-4-

[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid calcium salt (2:1)

Assignee:

Warner-Lambert Company

Accorded Benefit:

Provisional application 60/302,049

filed 29 June 2001

### Senior Party

Named Inventors:

Judith Aronhime, Israel Ramy Lidor-Hadas, Israel Valerie Niddam, Israel Revital Lifshitz, Israel Guy Sambursky, Israel

Application:

Application 09/997,126, filed 29 November 2001

Title:

Novel crystal forms of atorvastatin hemi-calcium and processes for their preparation as well as novel processes for preparing other forms

Assignee:

Teva Pharmaceutical Industries Ltd

Accorded Benefit:

Provisional application 60/267,897,

filed 09 February 20011

Aronhime also claims priority based on the following provisional applications:

<sup>(1)</sup> provisional application 60/250,072, filed 30 November 2000,

<sup>(2)</sup> provisional application 60/281,872, filed 05 April 2001,

<sup>(3)</sup> provisional application 60/312,144, filed 13 August 2001 and (4) provisional application 60/326,529, filed 01 October 2001.

If Aronhime thinks that it is entitled to benefit for the purpose of priority of one or more of these provisional applications, it may list a motion for benefit when it submits its motions list. 37 CFR § 41.204(b) (2005); 69 Fed. Reg. 50019 (Aug. 12, 2004). The files of these provisional applications are being maintained with the records of the interference; copies may be ordered directly with the board.

The senior party is assigned exhibit numbers 1001-1999. Bd. R. 154(c)(1).

The junior party is assigned exhibit numbers 2001-2999. Bd. R. 154(c)(1).

The senior party is responsible for initiating settlement discussions. STANDING ORDER  $\P$  18.

# Part F. Count and claims of the parties

### Count 1

A crystalline Form VIII atorvastatin hemi-calcium and solvates thereof characterized by a powder X-ray diffraction pattern generated using  $\text{CuK}_{\alpha}$  radiation with peaks at

4.8 5.2 8.0 9.2 9.6 19.0 20.0 24.0 and 29.0

### ± 0.2 degrees two-theta

or

a crystalline Form X atorvastatin or a hydrate thereof having an X-ray powder diffraction containing the following  $2\theta$  values measured using  $\text{CuK}_{\alpha}$  radiation:

4.7 5.2 5.8 6.9 7.9 9.2 9.5 10.3 (broad) 11.8 16.1 16.9 19.1 19.8 21.4 22.3 (broad) 23.7 (broad) 24.4 and 28.7.

The claims of the parties are:

Byrn:

1-15

Aronhime:

147-166

The claims of the parties which correspond to Count 1 are:

Byrn:

6

Aronhime:

147-166

The claims of the parties which do not correspond to

Count 1, and therefore are not involved in the interference, are:

Byrn:

1-5 and 7-15

Aronhime:

None

### Part G. Heading to be used on papers

The heading in STANDING ORDER Form 1 must be used on all papers filed in this interference. See STANDING ORDER  $\P$  7.2.1. The administrative patent judge and parties must be indicated as follows:

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

STEPHEN ROBERT BYRN, DAVID ANDREW COATES, KAREN SUE GUSHURST, JOSEPH FRANCIS KRZYZANIAK, ZHENG JANE LI, HENRY GRANT MORRISON II, AERI PARK and PETINKA IVANOVA VLAHOVA,

Junior Party (Patent 6,605,729 B1),

v.

JUDITH ARONHIME, RAMY LIDOR-HADAS, VALERIE NIDDAM, REVITAL LIFSHITZ and GUY SAMBURSKY,

Senior Party (Application 09/997,126).

Patent Interference No. 105,384--McK Technology Center 1600

# Part H. Order form for requesting file copies

When requesting copies of files, use of STANDING ORDER Form 4 will greatly expedite processing of the request. Please attach a copy of Part E of this DECLARATION with a hand-drawn circle around the patents and applications for which a copy of a file wrapper is requested.

Part I. Required paragraph for affidavits and declarations
The Board has recently experienced a rash of cases in which
a witness has belatedly advanced reasons why he or she would be
unable to appear for cross examination at a reasonable time and
place in the United States. Consequently, the Board is requiring
the following paragraph to be included on the signature page of
all affidavits (including declarations) filed in this case to
prevent surprise and hardship to the party relying on the
testimony of the witness:

In signing this affidavit/declaration, I recognize that the affidavit/declaration will be filed as evidence in a contested case before the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

/Fred E. McKelvey/2

FRED E. McKELVEY, Senior Administrative Patent Judge

07 October 2005 Alexandria, VA

<sup>&</sup>lt;sup>2</sup> As part of Board efforts under the Government Paperwork Elimination Act, signatures on papers originating from the Board are being phased out in favor of a completely electronic record. Consequently, in this case papers originating at the Board will not have signatures. The signature requirements for the parties have not changed. See, e.g., 37 CFR § 10.18.

### Enc (there is no Form PTO-850):

STANDING ORDER (Paper 2) DVD program e-filing program U.S. Patent 6,605,729 B1 Claims 147-166 of application 09/997,126 Specification, abstract and drawings (as filed) of application 09/997,126 Oath of application 09/997,126 Specification, oath, abstract and drawings (as filed) of application 10/860,084 Claims of application 10/860,084 Request under 37 CFR § 1.607 for declaration of an interference filed 28 July 2004 in application 09/997,126 Bibliographic data for applications 10/860,084 and 09/997,126 and 10/184,669

Revised January 2005

cc (via overnight delivery):

Attorney for Byrn (real party in interest Warner-Lambert Company):

Francis J. Tinney, Esq. WARNER-LAMBERT COMPANY 2800 Plymouth Road Ann Arbor, MI 48105

Tel: 734-622-7295 Fax: 734-622-1553

Email: None

Attorney for Aronhime (real party in interest Teva Pharmaceutical Industries Ltd):

Joseph A. Coppola, Esq. KENYON & KENYON 1500 K Street, N.W., Suite 700 Washington, D.C. 20005

Tel: 202-220-4215 (direct dial)

Fax: 202-220-4201

Email: None

Steven J. Lee, Esq. KENYON & KENYON One Broadway New York, NY 10004

Tel: 212-425-7200 (main) Fax: 212-425-5288 (fax)

Email: None